

REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

Claims 1, 6-7, and 33-37 are currently pending.¹ By the foregoing amendment, claims 1 and 33 have been amended such the cultured microorganism belongs to the "genus *Mortierella*, subgenus *Mortierella*". Support for this amendment can be found throughout the originally filed application including, for instance, page 7, line 32 through page 8, line 21. Thus no new matter has been added.

Claims 1, 7, 31-33, and 35-37 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which allegedly was not described in the specification in such a way as to reasonably convey to one skilled in the art that Applicants had possession of the claimed invention at the time the application was filed. In particular, the Examiner has asserted that "[n]o basis or support is found in the present specification for the production of 7 g/l arachidonic acid under conditions of the claim designated invention with any strain of the genus *Mortierella* or any member of the genus *Mortierella*, subgenus *Mortierella*." *Office Action* at 2. The Examiner goes on to state that the currently pending claims therefore "raise[s] the issue of new matter" Applicants respectfully traverse this rejection.

Regarding the written description requirement of 35 U.S.C. § 112, first paragraph, the Federal Circuit has clarified its earlier statement in *Vas-Cath* that

¹ While page 2 of the Office Action accurately indicates that claims 1, 6-7, and 31-37 have been examined, the Office Action summary incorrectly includes claims 3-5. It is noted that claims 3-5 were requested to be deleted in the amendment filed on December 16, 2002.

"[t]he purpose of the 'written description' requirement is . . . [to] convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath v. Mahurkar*, 935 F.2d at 1563-64, 19 USPQ2d at 1117. The court stated in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d at 1329, 63 USPQ2d at 1617:

That portion of the opinion in *Vas-Cath* . . . merely states a purpose of the written description requirement, *viz.*, to ensure that the applicant had possession of the invention as of the desired filing date. It does not state that possession alone is always sufficient to meet that requirement. Furthermore, in *Lockwood v. American Airlines, Inc.*, we rejected Lockwood's argument that "all that is necessary to satisfy the description requirement is to show that one is 'in possession' of the invention." 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Rather, we clarified that the written description requirement is satisfied by the patentee's disclosure of "such descriptive means as words, structures, figures, diagram, formulas, etc., that fully set forth the claimed invention." *Id.*

The court recently said in *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d at 1330, 65 USPQ2d at 1397:

The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required to "recount his invention in such detail that his future claims can be determined to be encompassed within his original creation." . . . [*Vas-Cath Inc. v. Mahurkar*, 935 F.2d] at 1561, 19 USPQ2d at 1115 Satisfaction of this requirement is measured by the understanding of the ordinarily skilled artisan. *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 41 USPQ2d 1961, 1966 (Fed. Cir. 1997) ("The description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). "Compliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'" *Enzo Biochem v. Gen-Probe, Inc.*, 296 F.3d 1316, 1324, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002).

These latest decision of the Federal Circuit restate the view expressed in *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997):

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

With that said, however, we must be mindful that "the invention claimed does not have to be described in *ipsis verbis* [in applicants' specification] in order to satisfy the description requirement of § 112." *In re Lukach*, 442 F.2d 967, 969, 169 USPQ 795, 796 (CCPA 1971).

Despite the Examiner's argument to the contrary, the Examiner has not shown that the present application, when considered as a whole, fails to satisfy the written description requirement of the first paragraph of 35 U.S.C. § 112.

The Examiner's citation of, and reliance on, *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d at 1327, 56 USPQ2d at 1487, is not outcome-determinative in this case.

The Examiner's citation and discussion regarding *Purdue Pharma L.P. v. Faulding Inc.* implies incorrectly that applicants "[fail] to describe a claimed generic concept in the narrative portion of the specification, but rather bas[e] support on limitations in examples." *Office Action* at 2. As discussed above, at least page 7, line 32 through page 8, line 21 describes the purported "generic concept" as claimed in the narrative portion of the specification. Therefore, persons having ordinary skill

in the art would have understood from applicants' original specification that applicants invented the subject matter claimed. *Enzo BioChem, Inc. v. Gen-Probe Inc.*, 296 F.3d at 1329, 63 USPQ2d at 1617; *Vas-Cath Inc. v. Mahurkar*, 935 F.2d at 1563-64, 19 USPQ2d at 1117. The examples, in particular Example 2, simply exemplify a specific embodiment of the claimed invention. Moreover, applicants need not establish that it actually reduced to practice every embodiment, or any embodiment for that matter, of the claimed invention to establish that it invented the claimed subject matter and this satisfied the written description requirement of the first paragraph of 35 U.S.C. § 112. *Enzo Biochem, Inc. v. Gen-Probe Inc.* 296 F.3d at 1329, 63 USPQ2d at 1617.

In view of the above, the Examiner is respectfully requested to withdraw the written description rejection.

Claims 1, 3-7 and 31-37 have been rejected under 35 U.S.C. § 112, second paragraph, as purportedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Applicants respectfully traverse this rejection.

As discussed above, claims 3-5 are not currently pending.

As to the alleged confusion with recitation of "species" and "sp." in claims 1 and 33, applicants have amended such claims to now recite the "genus *Mortierella*, subgenus *Mortierella*". Such amendments, which have been made to expedite prosecution and not to acquiesce to the Examiner's rejection, obviate this aspect of the rejection.

The amendment to claim 1 should also obviate the antecedent basis issue raised by the Examiner with regard to claim 6.

As to the Examiner's assertion that certain language in claims 31, 34, 35 and presumably 36 are vague and indefinite, applicants believe that one of ordinary skill in the art reading the claims in light of the specification would clearly understand what is meant by the language recited in such claims. The taxonomic categories and classes of microorganisms are well defined in microbiology textbooks.

In view of the above, withdrawal of the 35 U.S.C. § 112, second paragraph, rejection is respectfully requested.

Additionally, claims 1, 6-7, and 33-34 have been rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over Kyle (United States Patent No. 5,658,767)². This rejection is respectfully traversed.

The Examiner has asserted that "the strain of Kyle clearly grew in the medium used, which at least suggests that the strain is resistant to the carbon source provided." The lack of a "reasonable expectation of success" as required for an obviousness rejection notwithstanding, applicants' claimed invention is specified not only by the carbon source but also the productivity of arachidonic acid in the amount of "at least 7 g/L". Thus, while according to the examiner the Kyle patent describes the carbon source resistance, the Kyle patent does not teach or suggest the high productivity. For example, in Table 4, Stn 14, in the case where the starting glucose concentration was 11.6%, after 144 hours (6 days), the productivity of arachidonic acid is calculated as 1.75 g/L. In addition, in Table 4, Stn 15, in the case where the starting glucose was 11.3%, after 144 hours (6 days), the productivity of arachidonic acid was 4.09 g/L. In Table 5, in the case where the glucose concentration was 8%, after 237 hours (9.875 days), the productivity of arachidonic acid was 5.3 g/L.

² Applicants acknowledge the Examiner's statement that claims 6 and 34 "would be allowable if rewritten in independent form" *Office Action* at 5.

Since the Kyle patent fails to teach or suggest the productivity element of the claimed invention, a proper *prima facie* case of obviousness has been established. Therefore, withdrawal of this 35 U.S.C. § 103(a) rejection is respectfully traversed.


In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this Amendment and Reply, or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Respectfully submitted,

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